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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/699,302 | 10/30/2003 | Curt R. Freed | UTC-07994 | 3925 |
| 7590 Christine A. Lekutis MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105 | | 01/10/2007 | EXAMINER GAMETT, DANIEL C | |
| | | | ART UNIT 1647 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/10/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-----------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/699,302 | FREED ET AL. | |
| | Examiner Daniel C. Gamett, PhD | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09/25/2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6-10,16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 2, 4, 6-10, 16 and 18-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09/25/2006</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments of 09/25/2006 have been entered in full. Claims 3,5, 11-15, and 17 are cancelled. Claims 1, 2, 4, 6-10, 16 and 18-22 are under examination.
2. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

35 U.S.C. § 112

4. Claim 22 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection of record held, in part, that the specification did not provide adequate written description for the genus "at least one soluble molecule expressed by stromal cells". The claim has not been amended and this aspect of the rejection was not addressed in Applicant's arguments.
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 6-10, 16 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression, "human embryonic stem cell line co-cultured with fetal striatal cells" could mean either, "human embryonic stem cell line that *has been* co-cultured with fetal striatal cells" or "human embryonic stem cell line *in* co-culture with fetal striatal cells". By either interpretation, is not clear how recited

steps (a) and (b) of claim 1 are distinguished. Fetal striatal cells secrete GDNF, as evidenced by original claim 5 and current claim 6. Therefore, if one performs step (a), step (b) would necessarily happen every time, unless the striatal cells in step (a) are somehow prevented from expressing GDNF. In claim 16, the antecedent for “said cultured cells” in step (b) includes both the hES cells and the fetal striatal cells. Thus, the method indicates administration of fetal striatal cells to a patient. Likewise, the composition of claim 20 apparently comprises hES cells, striatal cells, and GDNF. None of this is consistent with Applicant’s invention, in view of the specification a whole. All remaining claims are indefinite as they depend from indefinite base claims.

Claim Rejections - 35 USC § 102

7. Claims 1,2, 4, 6,7, and 16 are rejected under 35 U.S.C. 102(e) as anticipated by US Patent 6833269 (Carpenter), filed May 31, 2001 Instant claim 1 is directed to a method of producing TH+ neurons from human embryonic stem cells (hES). As noted, the steps of the claimed method are unclear, but the method appears to comprise co-culturing a human embryonic stem cell line with fetal striatal cells and contacting hES cells with GDNF. The Carpenter patent teaches (throughout) derivation of neural cells from human embryonic stem cells. Carpenter teaches cultivation of hES in the presence of GDNF at column 13, line 63. Such cultivation would necessarily lead to all effects that are inherent to GDNF, including differentiation of TH+ neurons. Therefore, the only apparent distinction between Carpenter and instant claim 1, is the instant recitation of a “human

embryonic stem cell line co-cultured with fetal striatal cells". Fetal striatal cells secrete GDNF; co-culture with fetal striatal cells is a means for delivery of GDNF. The instant specification does not show that coculture with striatal cells imparts any characteristics to hES cells that are not also imparted by GDNF—either treatment results in formation of TH+ neurons when hES cells are grown on PA6 cells (figure 6F and figure 8). Therefore, "a human embryonic stem cell line co-cultured with fetal striatal cells" is indistinguishable from the product taught by Carpenter: a human embryonic stem cell line that has been treated with GDNF. This is not changed by any of the limitations on the source of GDNF recited in claims 2, 4, 6, or 7. Viewed this way, the instantly claimed method simply reiterates the treatment of the cells with GDNF (step (b)). Carpenter teaches treatment of Parkinson's disease at column 20, line 31, thereby anticipating claim 16.

8. The following is presented in order to clarify role of Applicant's amendment in this new grounds of rejection. Original claim 3, which recited co-culture with striatal cells, was interpreted as a means for accomplishing step (b) of claim 1. Even though Carpenter suggests contacting hES cells with GDNF and it would be obvious that striatal co-culture would be a way to deliver GDNF, there seems to be no motivation for doing it that way when purified GDNF is available. Thus, if the limitation of co-culture had been placed in step (b), the resultant method would be a non-obvious species of the generic contacting of hES cells with GDNF taught by Carpenter.

Conclusion

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9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
4 January 2007

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SUPERVISORY PATENT EXAMINER
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